

4. (Original) The composition of claim 3, wherein the microgel has a ratio of the macroviscosity of the microgel to the microviscosity of the microgel is 10,000 or less.

5. (Original) The composition of claim 1, wherein the polyanionic polymer is functionalized to provide one or more pendant functional groups selected from hydroxy, acyl halide, chloroformate, and mercapto; and wherein

the linking moiety provides crosslinking and is a reaction product of the pendant groups between polymer segments or between the pendant groups and complementing functions groups of a linking group.

6. (Original) The composition of claim 5, wherein the linking agent is the diacrylate of an  $\alpha,\omega$ -diol or the diacrylate of a chain extended  $\alpha,\omega$ -diol.

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#### REMARKS

After amendment, claims 1-6 remain pending in the present application. Claim 7 was canceled in the Response to the Restriction Requirement of January 7, 2003. No amendment has been made to distinguish over the art of record. A review of the present claims in comparison to the disclosures cited against the instant application evidences that the presently claimed compositions are clearly patentable over the disclosures of the cited art.

The Examiner has rejected claims 1-6 variously under 35 U.S.C. §112, second paragraph, §102 and §103 as being invalid for the reasons which have been stated in the office action. Applicants will address each of the Examiner's rejections in the sections which follow.

#### The §112, Second Paragraph Rejection

The Examiner has rejected claims under 35 U.S.C. §112, second paragraph for the reasons which have been made of record. In particular, the Examiner contends that the claims

are indefinite for having used the term “non-addition polyanionic polymer”. The Examiner contends that the term has not been defined in the specification, as have other terms used to describe the present invention.

Applicants respectfully traverse the Examiner’s rejection inasmuch as the term “non-addition polyanionic polymer” is clearly defined in the specification at page 10, 10 lines from the bottom as a “polymer wherein the polyanionic segments are not formed by the additional reaction of a strong nucleophile (excluding radicals) with an ethylenic unsaturation in a second molecule.” That same paragraph on page 10 of the specification provides exemplary polymerization which are non-addition reactions, including condensation reactions. It is respectfully submitted that the description of the term used in the claims, which appears in on page 10 of the specification obviates the Examiner’s rejection of the instant claims under 35 U.S.C. §112, second paragraph and claims 1-6 are in compliance with the requirements of 35 U.S.C. §112.

#### The §102/103 Rejection Based Upon the Cited Art

The Examiner has rejected claims 1-6 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Roth, et al., U.S. patent no. 5,999,475 (“Roth”), Kawai, et al., U.S. patent no. 5,302,312 (“Kawai”) or Williams, et al., British patent application GB 2,215,335 (“Williams”) for the reasons which are stated in the office action on pages 2-3. Essentially, it is the Examiner’s position that each of the above three references teach the claimed microgels made from acrylic acid monomers and containing the potential “anionic” entities as well as the cross-linking required by applicants’ claims. The Examiner notes that that the references are silent with respect to the specific properties of the microgels required, but he presumes them to have the same properties as the claimed microgels absent evidence to the contrary. Applicants respectfully traverse the Examiner’s rejection.

As set forth hereinabove, the present invention relates to novel compositions comprising a pre-formed hydrolytically susceptible non-addition polyanionic polymer which comprises polymer strands linked by at least one linking moiety comprising a hyrolytically susceptible

bond formed with a multidentate compound comprising two or more ethylenically unsaturated moieties, each such moiety being linked to the multidentate compound through a hydrolytically susceptible bond wherein the at least one of the monomers has at least one of functional groups or precursors of those functional groups which can be converted to the functional groups, the ethylenically unsaturated monomers according to the composition being described according to the formula set forth in claim 1. Applicants respectfully submit that the claimed compositions, which represent novel compositions for use in medical treatments or other applications as described in the specification, are novel and patentable over the cited art references.

None of the cited references, either alone or in combination teach or suggest the instant invention.

Roth does not disclose or suggest the present invention. Roth is directed to reactions products of an amine and a carboxyl function microgel which are to be used in epoxy resin systems. The Roth compositions contain amines (nitrogen-containing bases) as hardeners or as curing accelerators for the epoxy resins. The compositions disclosed in Roth do not anticipate the present invention, in the first instance, because the amine-containing accelerators of Roth (those compositions of Roth most relevant to the present invention) do not disclose or suggest the present invention and the combination of the amine-containing accelerators and the epoxy resin combinations are clearly not the present invention, nor do these compositions suggest the compositions of the present invention which find primary use in medical applications, in contrast to the . A review of Roth shows that the teachings of Roth do not make out the compositions according to the present invention.

Turning to Kawai, this reference does not disclose or suggest the present invention. Kawai is directed to a detergent for contact lens compounds which are designed for two purposes. The first is to increase the osmotic pressure caused by dissolving fine particles of water-soluble compounds into water at the time of washing a contact lens and the second is to reduce and/or eliminate dehydration of a contact lens caused by a disperse medium to suspend fine particles of water-soluble compounds and interaction of the disperse medium and the lens

(see column 2 of Kawai). It is apparent from the disclosure of Kawai that Kawai does not disclose the polymeric compositions which are claimed in the instant invention because no polymer disclosed meets the limitations of claim 1 of the instant invention. Regarding the question of obviousness, the compositions of Kawai, useful in formulating detergents for cleaning contact lenses clearly do not suggest the present compositions which find use in medical applications. Moreover, there is motivation to adapt the teachings of Kawai to those of the instant invention inasmuch as Kawai does not suggest the use of the compositions in medical applications, but rather as surfactants to clean contact lenses, a clearly distinguishable use. It is respectfully submitted that Kawai does not in any way render the present invention unpatentable.

Turning to Williams, it is respectfully submitted that this reference does not disclose or suggest the present invention. Williams is directed to immobilized enzymes conjugates soluble or dispersible in an organic solvent-containing medium prepared from a polymer microgel which contains significant hydrophobic groups, the polymer being conjugated via covalent linkages with the enzyme. A review of the chemistry of Williams with that of the claimed invention evidences that the present invention and the disclosed chemistry of Williams are not the same-Williams cannot therefore be construed as an invalidating (anticipating) reference. Regarding the question of obviousness, Williams cannot be an invalidating reference, inasmuch as it teaches a polymer to facilitate enzymatic reactions in organic solvents, an approach which is in apposite to the present invention and its direction of rendering polymeric compositions useful in medical applications. In short, Williams does nothing to invalidate the present invention or cure the clear deficiencies of the other cited art in failing to invalidate the present invention.

In sum, no cited reference or combination of references discloses or even remotely suggests the use of polymeric compositions according to the present invention. Consequently, it is respectfully submitted that the instant application is patentable.

It is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. For the above reasons, Applicant respectfully asserts that the claims set forth in the amendment to the application of the present invention are now in condition for

allowance and such action is earnestly solicited.

Applicant has neither added nor cancelled any claim. No fee is due for the presentation of this amendment. Small entity applies to the present application. A three month extension of time and a check in the amount of \$465.00 is enclosed . A revocation of power of attorney and appointment of substitute counsel is also enclosed as is an assignment document evidencing the transfer of this application to the new owner, Life Medical Sciences, Inc.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on September 15, 2003.

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